

CLAIMS

5 Sub A1  
1. A preparation for determining pyrimidine metabolizing activity, comprising as an active ingredient a pyrimidine compound or its metabolite in which at least one of C, O and N is labeled with an isotope.

10 2. A preparation according to claim 1, wherein the pyrimidine compound or its metabolite is a substrate for a pyrimidine metabolizing enzyme or a precursor of the substrate.

3. A preparation according to claim 2, wherein the pyrimidine metabolizing enzyme is at least one member selected from the group consisting of dihydropyrimidine dehydrogenase, dihydropyrimidinase and  $\beta$ -ureidopropionase.

15 Sub A2  
4. A preparation according to any one of claims 1 to 3, wherein the pyrimidine compound or its metabolite is at least one member selected from the group consisting of 5-fluorouracil, uracil, thymine, 5-fluorodihydrouracil, dihydrouracil, dihydrothymine, fluoro- $\beta$ -ureidopropionic acid,  $\beta$ -ureidopropionic acid,  $\beta$ -ureidoisobutyric acid, doxifluridine, tegafur and carmofur.

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25 5. A preparation according to any one of claims 1 to 4, wherein the pyrimidine compound or its metabolite is a compound in which at least one of C and O is labeled with an isotope, and wherein the pyrimidine compound or its metabolite is capable of producing isotope-labeled  $\text{CO}_2$ .

in vivo after administration.

6. A preparation according to any one of claims 1 to 5, wherein the isotope is at least one member selected from the group consisting of  $^{13}\text{C}$ ,  $^{14}\text{C}$ ,  $^{18}\text{O}$  and  $^{15}\text{N}$ .

5 7. A method for determining pyrimidine metabolizing activity in an individual subject, comprising administering a preparation according to any one of claims 1 to 6 to the subject, and measuring behavior of an isotope-labeled metabolite.

10 8. A method for determining pyrimidine metabolizing activity in an individual subject, comprising administering a preparation according to any one of claims 1 to 6 to the subject, and measuring excretion behavior of an isotope-labeled metabolite excreted from the body.

15 9. A method for determining pyrimidine metabolizing activity in an individual subject, comprising administering a preparation according to any one of claims 1 to 6 to the subject, and measuring behavior of isotope-labeled  $\text{CO}_2$  excreted in the expired air.

20 10. A method according to claim 7 or 8, wherein the pyrimidine metabolizing activity to be determined is an activity of at least one pyrimidine metabolizing enzyme selected from the group consisting of dihydropyrimidine dehydrogenase, dihydropyrimidinase and  $\beta$ -ureidopropionase.

25 11. A method for assessing pyrimidine metabolizing activity in an individual subject, comprising

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25 15. A method according to claim 14, wherein the  
pyrimidine drug is a fluorouracil drug selected from the

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cont

group consisting of 5-fluorouracil, tegafur, carmofur and  
doxifluridine.

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